Can the FDA Save Early Abortion?

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Greer Donley, *Early Abortion Exceptionalism*, 107 **Cornell L. Rev**. __ (forthcoming 2021), available on SSRN.

In *Early Abortion Exceptionalism*, forthcoming in the Cornell Law Review, Professor Greer Donley addresses the regulation of medication abortion by the U.S. Food and Drug Administration (FDA). Almost 40% of abortions are completed by taking two drugs at or before 10 weeks of gestation. Mifepristone is the first drug and, the second drug, misoprostol, is taken 24 to 48 hours after. The FDA issues a Risk Evaluation and Mitigation Strategy (REMS) for drugs it deems risky and in need of monitoring. Professor Donley focuses on two requirements this drug safety program imposes on providers seeking to prescribe mifepristone. For one, all providers must be certified to prescribe mifepristone, which requires submitting a form to the drug sponsor attesting that the provider can "assess the duration of pregnancy accurately," "diagnose ectopic pregnancies," and "provide surgical intervention" or "have made plans to provide such care through others." (P. 11.) For another, the FDA requires that patients collect mifepristone at a healthcare facility – in-person at a hospital, clinic, or medical office. The effect of the FDA's dispensation requirement has been to prohibit retail pharmacies and mail order prescription services from distributing mifepristone.

Professor Donley explains the complexities of the FDA regulation with clarity. But detailing the rules that govern medication abortion is not the point of her novel piece. Rather, Professor Donley assesses these restrictions in light of their ineffectiveness – medication abortion has been subject to strict controls even though it is comparatively safer than less regulated drugs. And she demonstrates why lifting these regulations would greatly expand access to early abortion. To make this case, her article offers three important insights.

First, Professor Donley shows how medication abortion, like other matters important to women's reproductive health, has been singled out among drugs and subject to an overly politicized process. Professor Donley compares the FDA's treatment of medication abortion to the agency's regulation of Plan B (the "morning after" pill), female sex drugs, and medical research in women and female animals. Together, these examples reveal "a troubling history of implicit bias that harms women, especially when considering reproductive health." (P. 36.)

Second, Professor Donley brings together legal arguments with public health research to demonstrate that medication abortion is safe and effective, highlighting that the FDA's requirements – certification and in-person dispensation specifically – are unnecessary at best and counterproductive for patient safety at worst. For example, of the 3.7 million women who took mifepristone between 2000 and 2018, the FDA's website notes that there were 24 deaths. Viagra, by contrast, has a fatality rate of 4 deaths per 100,000, nearly six times higher than that of mifepristone; but unlike mifepristone, Viagra is not subject to the same restrictions.

The COVID-19 pandemic highlights the mismatch between the safety of medication abortion and the burdensome FDA restrictions. Along with the expansion of telemedicine in numerous other areas, the pandemic has been a catalyst for the wider introduction of telehealth for medication abortion. In July 2020, a federal district court temporarily enjoined, for the course of the pandemic, the FDA restrictions

on how patients collect the drug regimen.[1] Professor Donley weaves together the arguments marshalled by the district court in suspending in-person dispensation with the proven benefits of "teleabortion" to urge the FDA to lift or to modify the REMS – an action that the FDA may take by the end of this year.

Third, Professor Donley reflects on the future of abortion care given the emergence of virtual clinics providing medication abortion services. Professor Donley argues that anti-abortion activists would have trouble challenging the FDA's removal of the REMS in court. More practically, despite clear limitations on the expansion of teleabortion – including state-specific restrictions on the delivery of medication abortion and bans on telemedicine for abortions – more people will receive medication abortions because of remote delivery. Mailing a two-drug regimen opens all manner of possibilities for abortion access, within and outside the law.

Professor Donley provides a fascinating and timely account of the changing legal landscape for medication abortion, blending various perspectives – from empirical research to agency review to litigation strategies – that are not often in conversation with each other. Removing federal restrictions will increase access to medication abortion; yet how big a difference remains to be seen. If pharmacies were to carry mifepristone, for example, Professor Donley suggests that more providers would administer medication abortion because they could avoid the costs of storing it. Professor Donley, however, may underestimate the various impediments to abortion care, which include limited medical training, stigma, or costly impact of state regulations. For instance, 19 states require some in-person component of having a medication abortion (such as in-person counseling or a mandated ultrasound); these state laws will impede the expansion of virtual medication abortion even if federal oversight is relaxed. States also are attempting to regulate mifepristone more strictly than the FDA; these efforts raise questions of federal preemption that are the subject of ongoing litigation. This is all to say that removing FDA restrictions would go a long way in expanding access to medication abortion, but it is only one piece of a complicated puzzle.

To be sure, Professor Donley recognizes the challenges ahead for expanding access to medication abortion. Her work is prescient while staying grounded in the history of the abortion debate at federal and state levels. But her optimism about the capacity of medication abortion to shore up gaps in access is contagious, particularly given the role that portable, inexpensive medication abortion might play in a country where some states double down on anti-abortion legislation. As the country awaits a 2022 Supreme Court decision on whether states may ban abortion before viability – a decision that likely will overturn or further eviscerate constitutional protection for abortion decisions — the legal landscape for abortion promises to shift further in the near future. *Early Abortion Exceptionalism* invites the federal government, as seems to be its direction, to solve the already-severe problem of how people gain access to abortion services, rather than to continue to exacerbate it.

1. Am. Coll. of. Obstetricians & Gynecologists v. FDA, 472 F. Supp. 3d 183 (D. Md. 2020).

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